

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

JAN 13 2006

Stephen B. Maebius Foley and Lardner Washington Harbour, Suite 500 3000 K Street NW Washington DC 20007-5109 In Re: Patent Term Extension Application for U.S. Patent No. 5,153,222

Dear Mr. Maebius:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,153,222 for a period of 5 years. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Telephone inquiries regarding this communication should be directed to Kathleen Fonda by telephone at (571)272-7754, or at Kathleen.Fonda@uspto.gov by e-mail.

Kery Fries

Senior Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc:

Office of Regulatory Policy

HFD - 13

5600 Fishers Lane Rockville, MD 20857

Attention: Claudia Grillo

RE: REMODULIN® (Treprostinil sodium)

FDA Docket No.: 03E-0245

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 5,153,222

(45) ISSUED : October 6, 1992

(75) INVENTOR : Anjaneyulu S. Tadepalli, et al.

(73) PATENT OWNER : United Therapeutics Corp.

(95) PRODUCT : REMODULIN® (Treprostinil sodium)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,153,222 based upon the regulatory review of the product REMODULIN® (treprostinil sodium) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 5 years

from October 6, 2009, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

Control of the contro

I have caused the seal of the United States Patent and Trademark Office to be affixed this 11th day of January 2006.

Jon W. Dudas

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office